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Quality of life in painful diabetic neuropathy patients following treatment with spinal cord stimulation

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Introduction

Diabetes mellitus is a chronic condition with an increasing prevalence estimated to be 4.4% worldwide in 2030, the equivalent to 366 million people. Around one-third of diabetic patients are expected to develop painful diabetic neuropathy (PDN), which is the most disabling and costly complication of diabetes.

Spinal cord stimulation (SCS) is a recognised neuromodulation technique for the management of neuropathic pains such as complex regional pain syndrome [1] and failed back surgery syndrome. [2] Recently it has been reported that SCS results in significantly reduced pain and improved quality of life in patients with refractory painful diabetic neuropathy.[3] The quality of life (QoL) analysis was based on the EQ-5D visual analogue scale scores. We have now evaluated QoL based on index values of the EQ-5D for the countries where this trial was conducted.

Methods

The methods used, patient demographics and results from the randomised controlled trial are reported elsewhere.[3] Quality of life was assessed using the EQ-5D questionnaire. Health-related quality of life was derived from participants' responses to the widely used EuroQoL EQ-5D-3L questionnaire. Responses were converted into single (utility) indices using the Dutch tariff. Paired samples t-test were conducted to evaluate within group QoL changes. An ANCOVA analysis was undertaken to compare QoL between the groups while adjusting for the baseline score. Changes in sub-categories of the EQ-5D-3L were evaluated through the Mann-Whitney test for between-group analyses and the Wilcoxon signed-rank test for within-group analyses. Statistical analyses were conducted using the statistical software STATA (Release 13; College Station, TX: StataCorp LP).

Results

No statistically significant improvements were observed for the CMP group between baseline and six-month follow-up for the VASPI, EQ-5D utility or EQ-5D VAS scores (Table 1). Statistically significant improvements were observed for all outcome measures for the patients in the SCS group between baseline and six-month follow-up. Patients randomised to SCS experience greater pain relief and grater improvement in QoL as measured by the EQ-5D utility scores and EQ-5D VAS than those patients randomised to CMP. The interaction between groups and QoL baseline score was not significant $F(1,50)=2.391$, $p=0.128$. The ANCOVA comparing QoL between groups while adjusting for the baseline score was significant $F(1,50) = 14.274$, $p<0.001$.

On the EQ-5D sub-categories, at six-months the patients randomised to SCS reported significant improvements in four out of five dimensions: mobility, usual activities, pain/discomfort and anxiety/depression when compared to baseline (Figure 1). Statistically significant differences were observed between groups for the pain/discomfort EQ-5D dimension.

Table 1. Pain and EQ-5D index scores the SCS and CMP treatment groups

	SCS (n = 40) (mean, SD)			CMP (n = 20) (mean, SD)	
	Baseline	Six-months		Baseline	Six-months
Pain VAS, mean (SD)	74.94 (12.15)	29.22 (27.49) **		66.94 (18.48)	66.44 (21.86) ^^^
EQ-5D, mean (SD)	0.25 (0.27)	0.65 (0.28) **		0.44 (0.31) ^^	0.44 (0.33) ^
EQ-5D VAS, mean (SD)	49.17 (19.07)	60.89 (23.38) *		47.12 (16.11)	40.53 (20.35)^^

CMP, conventional medical practice; SCS, spinal cord stimulation; VAS, visual analogue scale

*p < .05, **p < .0001 (within a group), ^p < .05, ^^p < .01, ^^^p < .0001 (between groups)

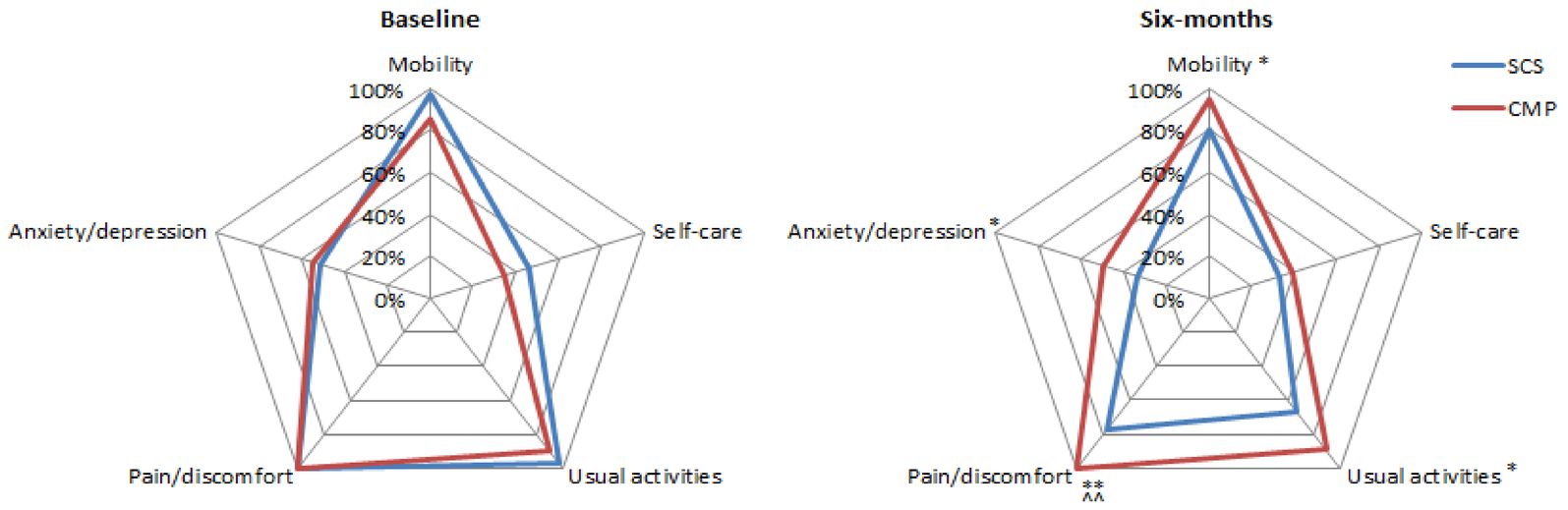

Figure 1. Comparison of proportion of patients reporting some problems or extreme problems in the EQ-5D subcategories

Conclusion

SCS has the potential to be an alternative for the management of refractory PDN. In addition to the significant reduction in pain observed in the de Vos et al RCT, SCS also appears to lead to significant improvements in QoL in this population. An economic evaluation is now in progress to evaluate the cost-effectiveness of SCS for the management of refractory PDN.

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